IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UROGEN PHARMA LTD. and UROGEN PHARMA, INC., Plaintiffs, v. TEVA PHARMACEUTICALS, INC. and TEVA PHARMACEUTICALS USA, INC., Defendants.	C.A. No. 24-417-JFM **ANDA CASE**

STIPULATION AND ORDER
REGARDING ASSERTED CLAIMS, DISCOVERY, AND INFRINGEMENT

WHEREAS Defendant Teva Pharmaceuticals, Inc. is the holder of ANDA No. 218215 for mitomycin for pyelocalyceal solution, 40 mg/vial;

WHEREAS by letter dated February 20, 2024 Teva Pharmaceuticals, Inc. notified Plaintiffs UroGen Pharma Ltd. and UroGen Pharma, Inc. (collectively, "Plaintiffs") that it submitted ANDA No. 218215 to the FDA and that, as part of its ANDA, it filed certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") for Plaintiffs' U.S. Patent Nos. 9,040,074 ("the '074 Patent") and 9,950,069 ("the '069 Patent");

WHEREAS Teva Pharmaceuticals, Inc.'s Paragraph IV Certification indicated that Teva Pharmaceuticals, Inc. was seeking FDA approval to engage in the commercial manufacture, use and/or sale of its proposed mitomycin for pyelocalyceal solution product described in ANDA No. 218215 ("Teva's ANDA Product") before the expiration of the '074 Patent and the '069 Patent;

WHEREAS Plaintiffs sued Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") for patent infringement on April 2, 2024 ("Plaintiffs' Complaint");

WHEREAS Teva filed an answer to Plaintiffs' Complaint and counterclaims on July 10,

2024;

WHEREAS Plaintiffs filed an amended complaint for patent infringement of U.S. Patent No. 12,268,745 ("the '745 Patent") on May 19, 2025 ("Plaintiffs' Amended Complaint");

WHEREAS Teva filed an answer to Plaintiffs' Amended Complaint and counterclaims on June 2, 2025 ("Teva's Answer");

WHEREAS the parties seek to narrow the issues for discovery, streamline the issues in the case, and reduce costs by entering into this stipulation; and

WHEREAS the parties agree that the interests of efficiency are best served by narrowing the scope of this action to the validity of claims 2, 3, and 12 of the '074 Patent, claims 2, 3 and 12 of the '069 Patent and claims 1 and 8 of the '745 Patent.

IT IS HEREBY STIPULATED AND AGREED by the parties, subject to the approval of the Court, that:

1. The claim terms for claims 1-8 of the '745 patent that relate to the percentage of poloxamer 407, hydroxypropylmethylcellulose and PEG-400 that comprise the thermoreversible hydrogel should be construed as the percentage (w/w) of those excipients present in the thermoreversible hydrogel prior to the incorporation of an effective amount of mitomycin C and accompanying mannitol.

2. Upon final approval of ANDA No. 218215, the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Teva's ANDA Product would infringe claims 2, 3, and 12 of the '074 Patent, claims 2, 3 and 12 of the '069 Patent and claims 1 and 8 of the '745 Patent, if these claims are valid.

3. In consideration of Teva's stipulation of infringement as set forth in Paragraph 2, Plaintiffs agree that the only patent claims that it will assert against Teva in this case are claims 2, 3, and 12 of the '074 Patent, claims 2, 3 and 12 of the '069 Patent and claims 1 and 8 of the '745 Patent.

4. In consideration of Teva's stipulation of infringement as set forth in Paragraph 2, Plaintiffs agree to withdraw Plaintiffs' requests for the production of documents and things to Defendants Nos. 3, 6-10, 14-15, 18 and 25-29.

5. Nothing in this stipulation shall preclude Teva from contesting the validity of claims 2, 3, and 12 of the '074 Patent, claims 2, 3 and 12 of the '069 Patent and claims 1 and 8 of the '745 Patent.

Dated: August 28, 2025

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IT IS SO ORDERED THIS 28th day of August, 2025

Honorable John F. Murphy
United States District Judge